IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. of: Jean-Louis Henri Dasseux, et al.			
Appln. No.:	10/596,047	Examiner:	Taofiq A. Solola
Filed:	June 21, 2006	Art Unit:	1625
For:	KETONE COMPOUNDS AND COMPOSITIONS FOR CHOLESTEROL MANAGEMENT AND RELATED USES	Conf. No.:	1170
Attorney Docket No.: 13657-30			

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT PURSUANT TO 37 C.F.R. § 1.705(b)

Mail Stop Patent Ext
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

A notice of allowance was issued for the present application on **March 31, 2009** indicating that the issue fee is due on **June 30, 2009**. The issue fee is being submitted for the present application in conjunction with this request for reconsideration of the patent term adjustment. The Patent Application Information Retrieval (PAIR) system and the notice of allowance both indicate a patent term adjustment that was calculated by the U.S. Patent and Trademark Office ("USPTO") pursuant to 37 C.F.R. 1.701 of **0** days. A copy of Notice of Allowance for the present application is included herewith as Exhibit A.

Applicant's Attorney believes that the patent term adjustment should be **14** days. For the reasons stated herein, reconsideration of the patent term adjustment is respectfully requested pursuant to 37 C.F.R. 1.705(b). Please charge the petition fee

pursuant to 37 C.F.R. § 1.18(e) to Deposit Account No. 23-1925. Please charge any additional fee required or credit for any excess fee paid to Deposit Account No. 23-1925.

The patent term adjustment for the present application was calculated by the USPTO based on activities and associated dates detailed in the Patent Application Information Retrieval (PAIR) system Patent Term Adjustment History, attached as Exhibit B. Applicant's Attorney believes that errors and/or omissions in the calculation and/or the PAIR system Patent Term Adjustment History may have resulted in an incorrect patent term adjustment for the present application as described in detail below. The present application is not subject to a terminal disclaimer.

Period of adjustment pursuant to 37 C.F.R. § 1.703

Period of adjustment pursuant to 37 C.F.R. § 1.703(a)(1)

The period of adjustment pursuant to 37 C.F.R. § 1.703(a)(1) is the number of days in the period beginning on the day ("the 14 month date") after that date that is fourteen months after the date on which the application was filed pursuant to 35 U.S.C. § 111(a), or fulfilled the requirements pursuant to 35 U.S.C. § 371, and ending on the date of mailing or either an action pursuant to 35 U.S.C. § 132 or a notice of allowance pursuant to 35 U.S.C. § 151, whichever comes first.

The present application was filed on **June 21, 2006**. The 14 month date specified in 37 C.F.R. § 1.703(a) is **August 21, 2007**. According to the PAIR system Patent Term Adjustment History, attached as Exhibit B, the first action on the merits by the U.S. Patent and Trademark Office in the present application was a **requirement for restriction** mailed on **December 31, 2007** (attached on Exhibit E, further described below). This period

represents a delay on the part of the U.S. Patent and Trademark Office of 132 days. However, the USPTO does not appear to have calculated any office delay for this time period. Thus, Applicant's Attorney believes that the difference between the 14 month date and the date of mailing of the first action on merits should have been **132** days. Applicant's Attorney respectfully requests calculation of USPTO delay for submitting the first office action on the merits and re-calculation of the patent term adjustment to take the corrected date into account.

Period of adjustment pursuant to 37 C.F.R. § 1.703(a)(2)

The period of adjustment pursuant to 37 C.F.R. § 1.703(a)(2) is the number of days in the period beginning on the day ("the 4 month date") after that date that is four months after the date on which a reply was filed pursuant to 35 U.S.C. § 111 and ending on the date of mailing of either an action pursuant to 35 U.S.C. § 132, or a notice of allowance pursuant to 35 U.S.C. § 151, whichever comes first.

In the present application, a reply was filed on **June 27, 2008** as evidenced by a copy of the Electronic Acknowledgement Receipt that is attached as Exhibit C. The 4 month date is therefore **October 27, 2008**. An office action in response to the reply was mailed by the U.S. Patent and Trademark office on **September 30, 2008** (Exhibit D attached). Applicant's Attorney believes that the difference between the 4 month date and the date of mailing of the office action is **0** days. Applicant's Attorney believes that no re-calculation of the period of adjustment pursuant to 37 C.F.R. § 1.703(a)(2) is necessary.

Reduction in Period of Adjustment pursuant to 37 C.F.R. § 1.704

Period of adjustment pursuant to 37 C.F.R. § 1.704(b)

Pursuant to 37 C.F.R. § 1.704(b), the period of adjustment shall be reduced by the number of days, if any, beginning on the day after the date (the 3 month date) that is three months after the date of mailing or transmission of an Office communication notifying the applicant of a rejection, objection, etc., and ending on the date a corresponding reply was filed.

In the present application, a requirement for restriction was mailed on **December 31, 2007** (attached as Exhibit E). The 3 month date was therefore **March 31, 2008**. A response by the Applicant's Attorney to the requirement for restriction was filed with the U.S. Patent and Trademark office on **June 27, 2008** as evidenced by the Electronic Acknowledgement Receipt attached as Exhibit F. Therefore, a delay of **88** days should be calculated against Applicants.

A second PTO action was mailed on **September 30, 2008**. The 3 month date was therefore **December 30, 2008**. A response by Applicant's Attorney to the second PTO action was filed on **January 29, 2009** (attached as Exhibit G). Therefore, an additional delay of **30** days should be lodged against the Applicant.

Period of adjustment pursuant to 37 C.F.R. § 1.704(c)(10)

Pursuant to 37 C.F.R. § 1.704(c)(10), when an amendment pursuant to 37 C.F.R. § 1.312 or other paper was submitted after a notice of allowance had been given or mailed, the period of adjustment shall be reduced by the number of days, if any, beginning on the date the amendment pursuant to 37 C.F.R. § 1.312 or other paper was submitted and ending on the mailing date of a supplemental office action or notice of allowance, or four months, whichever is less.

In the present application, there was no amendment filed pursuant to 37 C.F.R. § 1.312 or other paper was submitted after a notice of allowance had been given or mailed. Therefore no additional reduction for Applicant delay should be calculated.

Total patent term adjustment

For the present application, the total patent term adjustment pursuant to 37 C.F.R. § 1.703(f) is the period of adjustment pursuant to 37 C.F.R. § 1.703 reduced by any delays pursuant to 37 C.F.R. § 1.704. Thus, according to our calculations, we believe that the patent term adjustment should be (**132+0)** days - (**88+30)** days = **14** days, instead of **0** days indicated on the Notice of Allowance attached as Exhibit A.

It is respectfully asserted that the patent term adjustment determined by the U.S. Patent and Trademark Office for the present application may not be correct. Accordingly, Applicant's Attorney respectfully requests the U.S. Patent and Trademark office to reconsider, and make revisions to the PAIR system Patent Term Adjustment History in view of the previous remarks. In addition, it is respectfully requested that the patent term adjustment be re-calculated by the U.S. Patent and Trademark Office in view of the above remarks. Office personnel are invited to contact the undersigned attorney for the Applicant's Attorney via telephone if such communication would be beneficial in fulfilling this request.

Respectfully submitted,

June 26, 2009
Date

/William R. Boudreaux/
William R. Boudreaux
Registration No. 35,796
Attorney for Applicants

BRINKS HOFER GILSON & LIONE
524 S. Main
Ann Arbor, MI 48104
(734) 302-6000

EXHIBIT A

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

757 7590 03/31/2009

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER	
SOLOLA, TAOFIQ A	
ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 03/31/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,047	06/21/2006	Jean-Louis Henri Dasseux	PC20667	1170

TITLE OF INVENTION: KETONE COMPOUNDS AND COMPOSITIONS FOR CHOLESTEROL MANAGEMENT AND RELATED USES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	06/30/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) ~~to your deposit account, section "4b"~~ of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

757 7590 03/31/2009

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,047	06/21/2006	Jean-Louis Henri Dasseux	PC20667	1170

TITLE OF INVENTION: KETONE COMPOUNDS AND COMPOSITIONS FOR CHOLESTEROL MANAGEMENT AND RELATED USES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	06/30/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
SOLOLA, TAOFIQ A	1625	560-051000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,047	06/21/2006	Jean-Louis Henri Dasseux	PC20667	1170

757 7590 03/31/2009

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER	
SOLOLA, TAOFIQ A	
ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 03/31/2009

Determination of Patent Term Extension under 35 U.S.C. 154 (b)
(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Notice of Allowability	Application No.	Applicant(s)	
	10/596,047	DASSEUX ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to *the interview of 3/23/09*.

2. ☐ The allowed claim(s) is/are *58-59, 61-68, 70-80 (now 1-21 respectively)*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date na
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with William Boudreaux on 3/23/079

1. The following species are deleted from claim 58, 71 and 76.

~~Diethyl 10-oxo-2,2,18,18-tetramethyl-nonadecanedioate,~~
~~10-Oxo-2,2,18,18-tetramethyl-nonadecanedioic acid.~~

2. Claims 60 and 69 are deleted.

The Examiner confirms for the record that no interview tool place with applicant' representative on 2/13/09. Brief description of the figures is found on page 132 of the specification.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, 1625

March 24, 2009

FORM PTO-1449		SERIAL NO. 10/596,047	CASE NO. 13657-030
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		FILING DATE June 21, 2006	GROUP ART UNIT 1625
(use several sheets if necessary)	APPLICANT(S): Jean-Louis Henri Dasseux		CONFIRMATION NO. 1170

REFERENCE DESIGNATION **U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER Number-Kind Code (if known)	DATE	NAME	CLASS/ SUBCLASS	FILING DATE
	A1	US3441605	04/29/1969	Stephen Blake		
	A2	US3773946	11/20/1973	Paul L. Creger		
	A3	US3930024	12/30/1975	Paul L. Creger		
	A4	US4287200	09/01/1981	Yutaka Kawamatsu		
	A5	US4584321	04/22/1986	Elso Manghisi, et al.		
	A6	US4613593	09/23/1986	Isao Yamatsu, et al.		
	A7	US4634719	01/06/1987	Naotake Takaishi, et al.		
	A8	US4689344	08/25/1987	Jacob Bar-Tana		
	A9	US4711896	12/08/1987	Jacob Bar-Tana, et al.		
	A10	US5502198	03/26/1996	Joseph A. Picard, et al.		
	A11	US5504073	04/02/1996	Reynold Homan		
	A12	US5578639	11/26/1996	Reynold Homan		
	A13	US5633287	05/27/1997	Helen T. Lee, et al.		
	A14	US5648387	07/15/1997	Charles Larry Bisgaier, et al.		
	A15	US5750569	05/12/1998	Charles Larry Bisgaier, et al.		
	A16	US5756344	05/26/1998	Haruo Onda, et al.		
	A17	US5756544	05/26/1998	Charles Larry Bisgaier, et al.		
	A18	US5783600	07/21/1998	Charles Larry Bisgaier, et al.		
	A19	US5968963	10/19/1999	Reynold Homan		
	A20	US5981595	11/09/1999	Joseph A. Picard, et al.		
	A21	US6017905	01/25/2000	William Howard Roark, et al.		
	A22	US6093719	07/25/2000	Thomas M. A. Bocan		
	A23	US6093744	07/25/2000	Helen T. Lee, et al.		
	A24	US6124309	09/26/2000	Thomas M. A. Bocan		
	A25	US6143755	11/07/2000	Thomas M. A. Bocan		
	A25a	US6699910	03/02/2004	Jean-Louis Henri Dasseux, et al.		
	A25b	US2003/0078239	04/24/2003	Jean-Louis Henri Dasseux, et al.		

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER Number-Kind Code (if known)	DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES OR NO
	A26	WO9630328	10/03/1996	PCT		

EXAMINER /Taofiq Solola/	DATE CONSIDERED 03/18/2009

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.S./

FORM PTO-1449	SERIAL NO. 10/596,047	CASE NO. 13657-030
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	FILING DATE June 21, 2006	GROUP ART UNIT 1625
(use several sheets if necessary)	APPLICANT(S): Jean-Louis Henri Dasseux	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER Number-Kind Code (if known)	DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES OR NO
	A27	WO9830530	07/18/1998	PCT		
	A28	WO9900116	01/07/1999	PCT		
	A29	WO0064911	11/02/2000	PCT		
	A30	WO0146110	06/28/2001	PCT		
	A30a	WO0230860	04/18/2002	PCT		

EXAMINER INITIAL	OTHER ART – NON PATENT LITERATURE DOCUMENTS (Include name of author, title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published.	
	A31	Acton et al., 1996, "Identification of Scavenger Receptor SR-BI as a high density lipoprotein receptor", Science 271:518-520
	A32	Badimon et al., 1992, "Role of high density lipoproteins in the regression of atherosclerosis", Circulation 86(Suppl. III):86-94
	A33	Barrans et al., 1996 "Pre-beta HDL: structure and metabolism", Biochem. Biophys Acta 1300:73-85
	A34	Bisgaier et al., 1998, "A novel compound that elevates high density lipoprotein and activates the peroxisome proliferator activated receptor", J. Lipid Res. 39:17-30; (1998)
	A35	Brown and Goldstein, 1990, "Drugs used in the treatment of hyperlipoproteinemias", In: The Pharmacological Basis of Therapeutics, 8th Ed., Goodman & Gilman, eds., Pergamon Press, Ch. 36, pp. 874-896
	A36	Bruce et al., 1998, "Plasma lipid transfer proteins, high-density lipoproteins, and reverse cholesterol transport", Annu. Rev. Nutr. 18:297-330
	A37	Dansky and Fisher, 1999, "High-density lipoprotein and plaque regression: the good cholesterol gets even better", Circulation 100:1762-1763
	A38	Decossin et al., 1997, "Subclasses of LpA-I in coronary artery disease: distribution and cholesterol efflux ability, Eur. J. Clin. Invest. 27:299-307
	A39	Fielding and Fielding , 1995, "Molecular physiology of reverse cholesterol transport", J. Lipid Res. 36:211-228
	A40	Gearing et al., 1993, "Interaction of the peroxisome-prolifertor-activated receptor and retinoid X receptor", Proc. Natl. Acad. Sci. USA 90:1440-1444
	A41	Harris and Kletzien, 1994, "localization of pioglitazone response element in the adipocyte fatty acid-binding protein gene", Mol. Pharmacol. 45:439-445
	A42	Heyman et al., 1992, "9-cis retinoic acid is a high affinity ligand for the retinoid X receptor", Cell 68:397-406
	A43	Hidaka and Fidge, 1992, "Affinity purification of the hepatic high-density lipoprotein receptor identifies two acidic glycoproteins and enables further characterization of their binding properties", Biochem. J. 284:161-167
	A44	Hirano et al., 1997, "Genetic cholesterol ester transfer protein deficiency is extremely frequent in the Omagari area of Japan. Marked hyperalphalipoproteinemia caused by CETP gene mutation is not associated with longevity", Arterioscler, Thromb. Vasc. Biol. 17:1053-1059
	A45	Issemann and Green, 1990, "Activation of a member of the steroid hormone receptor superfamily by peroxisome proliferators", Nature 347:645-650

EXAMINER	/Taofiq Solola/	DATE CONSIDERED	03/18/2009

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.S./

FORM PTO-1449	SERIAL NO. 10/596,047	CASE NO. 13657-030
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	FILING DATE June 21, 2006	GROUP ART UNIT 1625
(use several sheets if necessary)	APPLICANT(S): Jean-Louis Henri Dasseux	

EXAMINER INITIAL	OTHER ART – NON PATENT LITERATURE DOCUMENTS (Include name of author, title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published.	
	A46	Keller and Wahli, 1993, "Peroxisome proliferator-activated receptors-a link between endocrinology and nutrition", TEM 4:291-296
	A47	Keller et al., 1993, "Fatty acids and retinoids control lipid metabolism through activation of peroxisome proliferator-activated receptor-retinoid X receptor heterodimers", Proc. Natl. Acad. Sci. USA 90:2160-2164
	A48	Kliewer et al., 1992, "Convergence of 9-cis retinoic acid and peroxisome proliferator signaling pathways through heterodimer formation of their receptors", Nature 358:771-774
	A49	Kurata et al., 1998, "A candidate high density lipoprotein (HDL) receptor, HB2, with possible multiple functions shows sequence homology with adhesion molecules", J. Atheroscler. And Thromb. 4:112-117
	A50	Lagrost et al., 1996, "Opposite effects of cholesterol ester transfer protein and phospholipid transfer protein on the size distribution of plasma high density lipoproteins. Physiological relevance in alcoholic patients", J. Biol. Chem. 271:19058-19065
	A51	Landschulz et al., 1996, "Regulation of scavenger receptor, class B, type I, a high density lipoprotein receptor, in liver and steroidogenic tissues of the rat", J. Clin. Invest. 98:984-995
	A52	Lazarow and Fujiki, 1985, "Biogenesis of peroxisomes", Annu. Rev. Cell Biol. 1:489-530
	A53	Levin et al., 1992, "9-cis retinoic acid stereoisomer binds and activates the nuclear receptor RXRα", Nature 355:359-361
	A54	Nemali et al., 1988, "Comparison of constitutive and inducible levels of expression of peroxisomal β-oxidation and catalase genes in liver and extrahepatic tissues of rat", Cancer Res. 48:5316-5324
	A55	Parra et al., 1992, "A case-control study of lipoprotein particles in two populations at contrasting risk for coronary heart disease. The ECTIM Study", Arterioscler. Thromb. 12:701-707
	A56	Reaven, 1993, "Role of insulin resistance in human disease (syndrome X): an expanded definition", Annu. Rev. Med. 44:121-131
	A57	Reddy and Lalwani, 1983, "Carcinogenesis by hepatic peroxisome proliferators: evaluation of the risk of hypolipidemic drugs and industrial plasticizers to humans", Crit. Rev. Toxicol. 12:1-58
	A58	Rigotti et al., 1996, "Regulation by adrenocorticotropic hormone of the in vivo expression of scavenger receptor class B type I (SR-BI), a high density lipoprotein receptor, in steroidogenic cells of the murine adrenal gland", J. Biol. Chem. 271:33545-33549
	A59	Robins and Fasulo, 1997, "High density lipoproteins, but not other lipoprotens, provide a vehicle for sterol transport to bile", J. Clin. Invest. 99:380-384
	A60	Staels and Auwerx, 1998, "Regulation of apo A-I gene expression by fibrates", Atherosclerosis 137(Suppl.):S19-S23
	A61	Tontonoz et al., 1994, "Adipocyte-specific transcription factor ARF6 is a heterodimeric complex of two nuclear hormone receptors, PPARγand RXRα", Nucl. Acids Res. 22:5628-5634
	A62	Vamecq and Draye, 1989, "Pathophysiology of peroxisomal β-oxidation", Essays Biochem. 24:115-225
	A63	Nan F et al. "Dual Function Glutamate-Related Ligands: Discovery of A Novel, Potent Inhibitor of Glutamate Carboxypeptidase II Possessing mGluR3 Agonist Activity" Journal of Medicinal Chemistry 2000, 43:pp. 772-774

EXAMINER	/Taofiq Solola/	DATE CONSIDERED	03/18/2009

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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EXHIBIT B

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10/596,047 KETONE COMPOUNDS AND COMPOSITIONS FOR CHOLESTEROL MANAGEMENT AND RELATED USES

Select New Case | Application Data | Transaction History | Image File Wrapper | Patent Term Extension History | Continuity Data | Published Documents | Address & Attorney/Agent | Assignments | Display References | Publication Review

Patent Term Extension

Filing or 371(c) Date:	06-21-2006	USPTO Delay (PTO) Delay (days):	0
USPTO Adjustment (days):	+0	Corrections (APPL) Delay (days):	0
Explanation Of Calculations		Total Patent Term Extension (days):	0

Patent Term Extension History

Date	Contents Description	PTO(Days)	APPL(Days)
03-31-2009	Mail Notice of Allowance		
03-27-2008	Document Verification		
03-27-2009	Notice of Allowance Data Verification Completed		
03-27-2009	Case Docketed to Examiner in GAU		
03-25-2009	Examiner's Amendment Communication		
01-29-2009	Information Disclosure Statement considered		
02-13-2009	Mail Examiner Interview Summary (PTOL - 413)		
02-10-2009	Examiner Interview Summary Record (PTOL - 413)		
02-05-2009	Date Forwarded to Examiner		
01-29-2009	Response after Non-Final Action		
01-29-2009	Request for Extension of Time - Granted		
01-29-2009	Information Disclosure Statement (IDS) Filed		
09-30-2008	Mail Non-Final Rejection		
09-26-2008	Non-Final Rejection		
07-30-2008	Date Forwarded to Examiner		
06-27-2008	Response to Election / Restriction Filed		
06-27-2008	Request for Extension of Time - Granted		
07-17-2008	Change in Power of Attorney (May Include Associate POA)		
07-16-2008	Correspondence Address Change		
12-31-2007	Mail Restriction Requirement		
12-26-2007	Requirement for Restriction / Election		
10-24-2007	Case Docketed to Examiner in GAU		
07-06-2007	IFW TSS Processing by Tech Center Complete		
07-05-2007	PG-Pub Issue Notification		
04-18-2007	Application Dispatched from OIPE		
06-24-2006	371 Completion Date		
04-05-2007	Sent to Classification Contractor		
04-05-2007	Notice of DO/EO Acceptance Mailed		

If you need help:

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EXHIBIT C

Electronic Acknowledgement Receipt

EFS ID:	3533099
Application Number:	10596047
International Application Number:	
Confirmation Number:	1170
Title of Invention:	Ketone compounds and compositions for cholesterol management and related uses
First Named Inventor/Applicant Name:	Jean-Louis Henri Dasseux
Customer Number:	28880
Filer:	William Robert Boudreaux/Diane Schmidt
Filer Authorized By:	William Robert Boudreaux
Attorney Docket Number:	PC20667
Receipt Date:	27-JUN-2008
Filing Date:	21-JUN-2006
Time Stamp:	15:42:17
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$2230
RAM confirmation Number	1145
Deposit Account	231925
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	13657_030_Signed_Power_of_Attorney_For_Filing.pdf	549014 5774d0d46a6acb57dbd6318b655bd6ebc5f3f9ee	no	2
Warnings:					
Information:					
2	Assignee showing of ownership per 37 CFR 3.73(b).	13657_030_Statement_Under_37_For_Filing.pdf	42727 8f74629bf41b97a9579d3a111d6953ed9681bab	no	1
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	13657_030_Assignment_Copy_For_Filing.pdf	885707 19adfc1e1e51a7a75cf7180b115e97ac029d92a2	no	6
Warnings:					
Information:					
4	Extension of Time	13657_030_Petition_for_Extension_of_Time_For_Filing.pdf	94856 68070a4878d369721d9312c2be2e9a9349a7a7a3	no	2
Warnings:					
Information:					
5		13657_30_Response_to_12_31_2007_Election_For_Filing.pdf	186215 e10a6bf47c402f961b285838e2f667279f372fe7	yes	10

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment - After Non-Final Rejection	1	1
Claims	2	5
Applicant Arguments/Remarks Made in an Amendment	6	10

Warnings:					
Information:					
6	Fee Worksheet (PTO-06)	fee-info.pdf	8213 d641cb9c4b76117c72cecd67a4bf11296290d965	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	1766732

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

EXHIBIT D

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,047	06/21/2006	Jean-Louis Henri Dasseux	PC20667	1170

757 7590 09/30/2008

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER	
SOLOLA, TAOFIQ A	
ART UNIT	PAPER NUMBER
1625	
MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,047	DASSEUX ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *27 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *34,36 and 56-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *58-69* is/are allowed.

6)☐ Claim(s) *36,56 and 57* is/are rejected.

7)☐ Claim(s) *34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *26 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *na*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Receipt date: 05/26/2006

Confirmation No.

PTO/SB/08A (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Jean-Louis Henri Dasseux
Art Unit	
Examiner Name	
Attorney Docket Number	PC20667

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 3,441,605A	04-29-1969	Stephen Blake	
		US- 6,699,910B2	03-02-2004	Jean-Louis Dasseux	
		US- 2003-0078239A1	04-24-2003	Jean-Louis Dasseux	
		US- 2004-0198814A2	10-07-2004	Jean-Louis Dasseux	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		WO02/30860A	04-22-2002	Dasseux et al		
		WO00/64911A	11-02-2000	Kozikowski et al		
		WO01/46110A	06-28-2001	Bowen et al		

Examiner Signature	/Taofiq Solola/	Date Considered	09/24/2008

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Jean-Louis Henri Dasseux
Art Unit	
Examiner Name	
Attorney Docket Number	PC20667

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		NAN et al., Dual function glutamate-related ligands: discovery of a novel, potent inhibitor of glutamate carboxypeptidase II possessing mGluR3 agonist activity, Journal of Medicinal Chemistry, pgs. 772-774, Vol. 43, No. 5, 2000	
		Search Report for PCT/US/03/41448	

Examiner Signature	/Taofiq Solola/	Date Considered	09/24/2008

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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.S./

Receipt date: 05/26/2006

PC 20667

UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: Confirmation No.:

Applicants: Jean-Louis Henri Dasseux, et al.

Filed:

TC/A.U.:

Examiner:

Docket No.: PC20667

Customer No.: 28880

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b)

Dear Sir:

The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of the first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

It is requested that the references listed on the attached form PTO-SB-08A and PTO-SB-08B be included in the "References Cited" portion of any patent issuing from this application (MPEP § 1302.12).

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. §1.131 or otherwise, to establish that

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the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Applicants also point out the following pending application:

US Serial Number 10/743,952

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form PTO-SB-08A and PTO-SB-08B, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

It is understood by the Applicants that this paper requires no fee; however, authorization is given to charge any necessary filing fees and any additional fees or credit any overpayment to Deposit Account 23-0455.

Respectfully submitted,

Dated: 25 May 2006

William R. Boudreaux
Registration No. 35,796
Pfizer, Inc.
2800 Plymouth Road
Ann Arbor, MI 48105
Telephone: (734) 622-1363
Facsimile: (734) 622-1553

 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.S./

Claims 34, 36, 56-59 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36, 56-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to treating or preventing cardiovascular diseases, disorders capable of being treated or prevented by increasing HDL or decreasing LDL levels. These are not practical utilities under the US patent practice. To ascertain the practical utility, one must read the specification into the claims contrary to several precedent decisions by the US courts and Official practice. The claims are attempts by applicant to claim treatment of all diseases known today and that may be discovered in the future, by increasing HDL or decreasing LDL levels. Cardiovascular diseases embrace many diseases. They are reach-through claims and are no longer patentable under the US patent practice. A claim must stand alone to define the invention, and incorporation into the claims by reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993). By deleting the terms the rejection would be overcome.

Claims 36, 56-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the claimed mechanisms and the diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

"'In the context of determining whether sufficient "utility as a drug, medicant, and the like in human therapy" has been alleged, It is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the [compounds and the utilities] as obviously correct." *In re Jolles*, 628 F.2d 1327, 1332 (Fed. Cir. 1980), citing *In re Novak*, 306 F.2d 924 (CCPA 1962); see 340 F.2d 974, 977-78 (CCPA 1965).

"A specification disclosure which contains a teaching of the manner and process of making and using the invention . . . must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), Id. at 1566, quoting *Marzocchi*, 439 F.2d 220, 223 (CCPA 1971); *Fiers v. Revel,* 984 F.2d 1164, 1171-72 (Fed. Cir. 1993), quoting *Marzocchi*, 439 F.2d at 223; see also *Armbruster*, 512 F.2d 676, 677 (CCPA 1975); *Knowlton*, 500 F.2d 566, 571 (CCPA 1974); *Bowen*, 492 F.2d 859 (CCPA 1974); *Hawkins*, 486 F.2d 569, 576 (CCPA 1973).

Where there is "no indication that one skilled in the art would accept without question [the instant compounds and method of use] and no evidence has been presented to demonstrate that the claimed products do have those effects *Novak*, 306 F.2d at 928, an applicant has failed to sufficiently demonstrate sufficient utility and therefore cannot establish enablement.'" *In re Rasmusson,* 75 USPQ2d 1297 (CAFC 2005). The claimed invention is not enabled without undue experimentation for the following reasons:

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered. *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988): "The factors to be considered [in making an enablement rejection] have been summarized as a) the breadth of the claims, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and, the quantity of experimentation necessary, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex prate Formal*, 230 USPQ 546. The breadth of the claims includes many compounds. The nature of the invention is using the compounds as pharmaceuticals. There is no known prior art that broadly teaches treating or preventing cardiovascular diseases, disorders capable of being treated or prevented by increasing HDL or decreasing LDL levels.

According to the specification the compounds are for treating lipidemia. Not every instance of lipidemia leads to all known cardiovascular diseases. The specification fails to disclose how "normal' patients who are predisposed to these unnamed diseases would be identified and treated before developing the unnamed diseases.

It is quite possible that a mutation in the gene for the lipid metabolism or synthesis may lead to decrease or increase levels of HDL and/or LDL. To use the invention as claimed, one of ordinary skill in the art would have to perform experimentation in every instance to determine if the decrease or increase is due to genetic mutation in a patient or not. After prospective patients are identified and treated, assays must be performed on each one to determine if treatment is successful. However, the specification fails to disclose a routine procedure to perform such assays. Therefore, to make and use the instant invention, one of ordinary skill in the art would have to perform significant amount of experimentations. Such is deemed undue experiment under the US patent practice.

There are no disclosures in the specification establishing a link between the activities of the instant compounds and all known cardiovascular diseases, disorders capable of being treated or prevented by increasing HDL or decreasing LDL levels. There is no absolute predictability or established correlation between the claims and the specification disclosures. The uncertainty presents one of ordinary skill in the art with obstacles and prevents her from accepting the invention on its face. Predictability in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. In the instant invention, there is no direction or guidance by applicant because assays are not performed for establishing nexus between the assays' result and specific disorders. The specification several diseases but they are mere speculations because there is no conclusive evidence of relationships between the compounds and all known cardiovascular diseases, disorders capable of being treated or prevented by increasing HDL or decreasing LDL levels. Therefore, there is no evidence in the specification that established correlation between the disclosure and the instantly claimed invention. *See Ex parte Mass*, 9 USPQ2d 1746, (1987).

MPEP 2164.01(a) states, "[a] conclusion of lack of enablement means that, based on the evidence regarding any of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. By limiting the disease to rheumatoid arthritis the rejection would be overcome.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 36, 56-57, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For the reasons set forth above under 35 USC 112, first paragraph the claims are indefinite. See the Examiner's suggestions above.

Objection

Claims 34, 36, 56-57 are objected to for depending from a subsequent claim. See the MPEP.

Allowable Subject Matter

Claims 58-69 are allowable over prior arts of record.

Related Patents

Numerous species are claimed in related patents, e.g. 6,699,910; 7,304,093; 7,119,221; 7,335,689 and 7,335,799. Applicant must delete such species form the instant claims.

Specification

There is no brief description of the drawing in the specification.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, Art Unit 1625

September 25, 2008

EXHIBIT E

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,047	06/21/2006	Jean-Louis Henri Dasseux	PC20667	1170

28880 7590 12/31/2007
WARNER-LAMBERT COMPANY
2800 PLYMOUTH RD
ANN ARBOR, MI 48105

EXAMINER	
SOLOLA, TAOFIQ A	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
12/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,047	DASSEUX ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-57 are pending in this application.

DETAILED ACTION

Election/Restriction

Claims 1-57 are drawn to more than one inventive concept (as defined by PCT Rule 13) and, accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that □special technical features□ mean those technical features which, as a whole, define a contribution over the prior art (novelty/unobviousness).

I. Claims 1-14, 19, 34-35, drawn to compound I, examples 1, 10, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

II. Claims 1-14, 19, 34-35, drawn to compound I, examples 2-5, 11-14, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

III. Claims 1-14, 19, 34-35, drawn to compound I, examples 6-7, 15-16, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

IV. Claims 1-14, 19, 34-35, drawn to compound I, examples 8-9, 17-18, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

V. Claims 15-17, 34-35, drawn to compound Ib, examples 1-5, 25-28, 50-52, 54-55, 59-63, 83-86, 106-109, 119-122, 144-147, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

VI. Claims 15-17, 34-35, drawn to compound Ib, examples 6-7, 29-30, 56-57, 64-65, 87-88, 110-111, 123-124, 148-149, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

VII. Claims 15-17, 34-35, drawn to compound Ib, examples 8-9, 31-32, 53, 58, 66-67, 89-90, 112-113, 125-126, 157-158, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

VIII. Claims 15-17, 34-35, drawn to compound Ib, examples 10-11, 33-34, 68-69, 91-92, 114-115, 127-128, 150-151, 159-160, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

IX. Claims 15-17, 34-35, drawn to compound Ib, examples 12, 35, 70, 93, 116, 129, 152, 161, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

X. Claims 15-17, 34-35, drawn to compound Ib, examples 13-14, 36-37, 71-72, 94-95, 117-118, 130-131, 153-154, 162-163, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XI. Claims 15-17, 34-35, drawn to compound Ib, examples 15-16, 38-39, 73-74, 96, 132-133, 155-156, 164-165, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XII. Claims 15-17, 34-35, drawn to compound Ib, examples 17-18, 40-41, 75-76, 97-98, 134-135, 166-167, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XIII. Claims 15-17, 34-35, drawn to compound Ib, examples 19-20, 42-44, 77-78, 99-101, 136-138, 168-170, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XIV. Claims 15-17, 34-35, drawn to compound Ib, examples 21-24, 45-49, 79-82, 102-105, 139-143, 171-175, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XV. Claims 18, 34-35, drawn to compound Ic, examples 1, 12, 23, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XVI. Claims 18, 34-35, drawn to compound Ic, examples 2-11, 13-22, 24-33, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XVII. Claims 20, 34-35, drawn to compound II, examples 1-11, 16-17, 22-39, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XVIII. Claims 20, 34-35, drawn to compound II, examples 12-13, 18-19, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XIX. Claims 20, 34-35, drawn to compound II, examples 14-15, 20-21, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XX. Claims 20, 34-35, drawn to compound II, examples 40-41, 45-46, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXI. Claims 20, 34-35, drawn to compound II, examples 42, 47, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXII. Claims 20, 34-35, drawn to compound II, examples 43-44, 48-49, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXIII. Claims 20, 34-35, drawn to compound II, examples 50-51, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXIV. Claims 20, 34-35, drawn to compound II, examples 52-53 and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXV. Claims 20, 34-35, drawn to compound II, examples 54-58, 60, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXVI. Claims 20, 34-35, drawn to compound II, example 59 and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXVII. Claims 21-25, 34-35, drawn to compound IIa, examples 1-11, 16-35, 22-39, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXVIII. Claims 21-25, 34-35, drawn to compound IIa, examples 12-13, 36-37, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXIX. Claims 21-25, 34-35, drawn to compound IIa, example 38 and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXX. Claims 21-25, 34-35, drawn to compound IIa, examples 39-40 and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXXI. Claims 21-25, 34-35, drawn to compound IIa, examples 41-42, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXXII. Claims 21-25, 34-35, drawn to compound IIa, examples 43-44 and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXXIII. Claims 21-25, 34-35, drawn to compound IIa, example 45 and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXXIV. Claims 21-25, 34-35, drawn to compound IIa, examples 46-50, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXXV. Claims 26-29, 34-35, drawn to compound III, examples 1-3, 7-9, 31-33, 37-39, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXXVI. Claims 26-29, 34-35, drawn to compound III, examples 4-6, 10-12, 34-36, 40-42, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXXVII. Claims 26-29, 34-35, drawn to compound III, examples 13-15, 22-24, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXXVIII. Claims 26-29, 34-35, drawn to compound III, examples 16-18, 25-27, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XXXIX. Claims 26-29, 34-35, drawn to compound III, examples 19-21, 28-30, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XL. Claims 26-29, 34-35, drawn to compound III, examples 43-45, 52-54, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XLI. Claims 26-29, 34-35, drawn to compound III, examples 46-47, 55-56, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XLII. Claims 26-29, 34-35, drawn to compound III, examples 49-51, 57-60, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XLIII. Claims 26-29, 34-35, drawn to compound III, examples 61-66, 85-87, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XLIV. Claims 26-29, 34-35, drawn to compound III, examples 67-84, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XLV. Claims 30-35, drawn to compound IIIa, examples 1-12, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XLVI. Claims 30-35, drawn to compound IIIa, examples 13-15, and composition thereof, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XLVII. Claims 1-14, 19, 34-35, drawn to none of the examples above but other compounds within the scope of the claims. The compounds must be disclosed in the specification. Structures of the compounds must be submitted and if more than one species a generic formula embracing all the species must also be submitted. This group may be subject to further restriction.

XLVIII. Claims 15-17, 34-35, drawn to none of the examples above but other compounds within the scope of the claims. The compounds must be disclosed in the specification. Structures of the compounds must be submitted and if more than one species a generic formula embracing all the species must also be submitted. This group may be subject to further restriction.

XLIX. Claims 18, 34-35, drawn to none of the examples above but other compounds within the scope of the claims. The compounds must be disclosed in the specification. Structures of the compounds must be submitted and if more than one species a generic formula embracing all the species must also be submitted. This group may be subject to further restriction.

L. Claims 20, 34-35, drawn to none of the examples above but other compounds within the scope of the claims. The compounds must be disclosed in the specification. Structures of the compounds must be submitted and if more than one species a generic formula embracing all the species must also be submitted. This group may be subject to further restriction.

LI. Claims 21-25, 34-35, drawn to none of the examples above but other compounds within the scope of the claims. The compounds must be disclosed in the specification. Structures of the compounds must be submitted and if more than one species a generic formula embracing all the species must also be submitted. This group may be subject to further restriction.

LII. Claims 26-29, 34-35, drawn to none of the examples above but other compounds within the scope of the claims. The compounds must be disclosed in the specification. Structures of the compounds must be submitted and if more than one species a generic formula embracing all the species must also be submitted. This group may be subject to further restriction.

LIII. Claims 30-35, drawn to none of the examples above but other compounds within the scope of the claims. The compounds must be disclosed in the specification. Structures of the compounds must be submitted and if more than one species a generic formula embracing all the species must also be submitted. This group may be subject to further restriction.

LIV. Claims 36-57, drawn to methods of using compounds of groups I-LIII, classifiable in several non-heterocyclic classes (514, 558, 562, etc.), numerous subclasses.

In the instant inventions, the only structural element shared by groups I-LIV is carboxyl group. However, carboxyl group is not novel. Therefore, under PCT Rules 13.1 and 13.2, carboxyl group does not constitute a corresponding special technical feature among the groups.

If applicant elects the invention of group LIV, one of groups I-LIII must be elected and group LIV would be examined commensurate in scope therewith.

If applicant elects the invention of group LIV or in a rejoinder thereof applicant must elect a specific disease and group LIV would be examined commensurate in scope therewith.

In an election of any of groups I-LIV, a single compound (or set of compounds) an exact definition of each substitution on the base molecule (Formula I), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R1, wherein R1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must select a single substituent of R1, for example OH or aryl, at each subsequent variable position.

In the instant case, Applicant must elect one representative for G, W1-W2, m, etc., in the applicable formula, and the point of attachment of each elected substituent must be specified. The elected substituents must be specific not generic so as to define a species. Applicant must provide the structure of the species. The species must be disclosed in the specification. The parts of the elected species corresponding to the substituents in formula I must be identified.

In a telephone call made to John Engelmann on 12/12/07, to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner before the patent issues withdraws the restriction requirement. See MPEP § 804.01.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1625

December 17, 2007

EXHIBIT F

CERTIFICATE OF EFS FILING UNDER 37 CFR §1.8

I hereby certify that this correspondence is being electronically transmitted to the United States Patent and Trademark Office, Commissioner for Patents, via the EFS pursuant to 37 CFR §1.8 on the below date:

Date: June 27, 2008 Name: William R. Boudreaux Signature: /WRB/

Case No. 13657-
Client Ref. No. PC20667US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Jean-Louis Dasseux et al.	Examiner: Taofiq A. Solola
Serial No: 10/596,047	Group Art Unit: 1625
Filed: June 21, 2006	Conf. No.: 1170
For: Ketone Compounds and Compositions for Cholesterol Management and Related Uses	

REPLY TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Restriction Requirement mailed December 31, 2007, Applicants provide the following election and comments. A request for five month extension of time authorization to pay the appropriate fee is submitted herewith.

Amendments to the Claims are reflected in the listing of the claims which begin on page 2 of this paper.

Remarks begin on page 6 of this paper.

Applicants note that the Transmittal to which this paper is attached includes a Certificate under 37 C.F.R § 1.8; and a fee statement calculating any fee(s) presently due in connection with the filing of this paper, along with an authorization to charge any fee deficiency to Deposit Account No. 23-1925.

In the Claims:

Please amend the Claims as follows (the changes in these Claims are shown with ~~strikethrough~~ for deleted matter and underlines for added matter). A complete listing of the claims proper claim identifiers is set forth below.

Claims 1 – 33 (canceled).

Claim 34 (currently amended). A pharmaceutical composition comprising a compound of claim ~~9~~ 58 or a pharmaceutically acceptable salt, hydrate, or solvate thereof and a pharmaceutically acceptable carrier.

Claim 35 (canceled).

Claim 36 (currently amended). A method for treating or preventing a cardiovascular disease in a patient, comprising administering to a patient in need of such treatment or prevention a therapeutically effective amount of a compound of claim ~~9~~ 58 or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claims 37 – 55 (canceled).

Claim 56 (currently amended). A method of treating or preventing a disease or disorder that is capable of being treated or prevented by increasing HDL levels, which comprises administering to a patient in need of such treatment a therapeutically effective amount of a compound of claim ~~9~~ 58 or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 57 (currently amended). A method of treating or preventing a disease or disorder that is capable of being treated or prevented by lowering LDL levels, which comprises administering to a patient in need of such treatment a

therapeutically effective amount of a compound of claim ~~9~~ 58 or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 58 (previously presented). A compound or pharmaceutically acceptable salt, hydrate, or solvate thereof selected from:

t-Butyl 1-[9-[1-(tert-butoxycarbonyl)cyclopropyl]-5-oxononyl]-1-cyclopropanecarboxylate,
Diethyl 10-oxo-2,2,18,18-tetramethyl-nonadecanedioate,
11-(1-Carboxycyclopropyl)-2,2-diemethyl-7-oxoundecanoic acid,
1-[9-(1-Carboxycyclopropyl)-5-oxononyl]-1-cyclopropanecarboxylic,
11-(1-Carboxycyclobutyl)-2,2-dimethyl-7-oxoundecanoic acid,
1-[9-(1-Carboxycyclobutyl)-5-oxononyl]-1-cyclobutanecarboxylic acid,
1-[9-(1-Carboxycyclopentyl)-5-oxononyl]-1-cyclopentylcarboxylic acid,
13-(1-Carboxycyclopropyl)-2,2-dimethyl-8-oxotridecanoic acid,
1-[11-(1-Carboxycyclopropyl)-6-oxoundecyl]-1-cyclopropane carboxylic acid,
1-[11-(1-Carboxycyclopentyl)-6-oxoundecyl]-1-cyclopentane carboxylic acid,
10-Oxo-2,2,18,18-tetramethyl-nonadecanedioic acid.

Claim 59 (previously presented). A compound of claim 58 wherein said compound is *t*-Butyl 1-[9-[1-(tert-butoxycarbonyl)cyclopropyl]-5-oxononyl]-1-cyclopropanecarboxylate, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 60 (previously presented). A compound of claim 58 wherein said compound is Diethyl 10-oxo-2,2,18,18-tetramethyl-nonadecanedioate, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 61 (previously presented). A compound of claim 58 wherein said compound is 11-(1-

Carboxycyclopropyl)-2,2-diemethyl-7-oxoundecanoic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 62 (previously presented). A compound of claim 58 wherein said compound is 1-[9-(1-

Carboxycyclopropyl)-5-oxononyl]-1-cyclopropanecarboxylic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 63 (previously presented). A compound of claim 58 wherein said compound is 11-(1-

Carboxycyclobutyl)-2,2-dimethyl-7-oxoundecanoic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 64 (previously presented). A compound of claim 58 wherein said compound is 1-[9-(1-

Carboxycyclobutyl)-5-oxononyl]-1-cyclobutanecarboxylic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 65 (previously presented). A compound of claim 58 wherein said compound is 1-(9-(1-

Carboxycyclopentyl)-5-oxononyl]-1-cyclopentylcarboxylic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 66 (previously presented). A compound of claim 58 wherein said compound is 13-(1-

Carboxycyclopropyl)-2,2-dimethyl-8-oxotridecanoic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 67 (previously presented). A compound of claim 58 wherein said compound is 1-[11-(1-Carboxycyclopropyl)-6-oxoundecyl]-1-cyclopropane carboxylic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 68 (previously presented). A compound of claim 58 wherein said compound is 1-[11-(1-Carboxycyclopentyl)-6-oxoundecyl]-1-cyclopentane carboxylic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

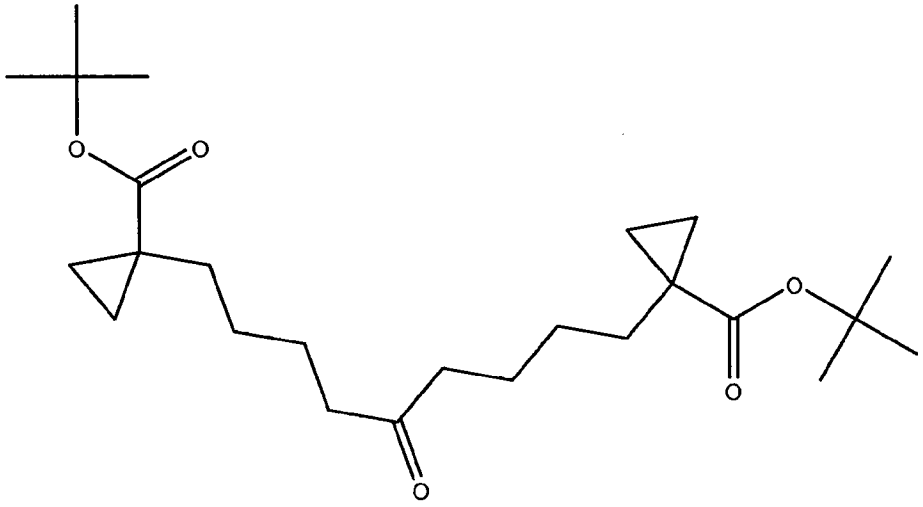
Claim 69 (previously presented). A compound of claim 58 wherein said compound is 10-Oxo-2,2,18,18-tetramethyl-nonadecanedioic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

REMARKS

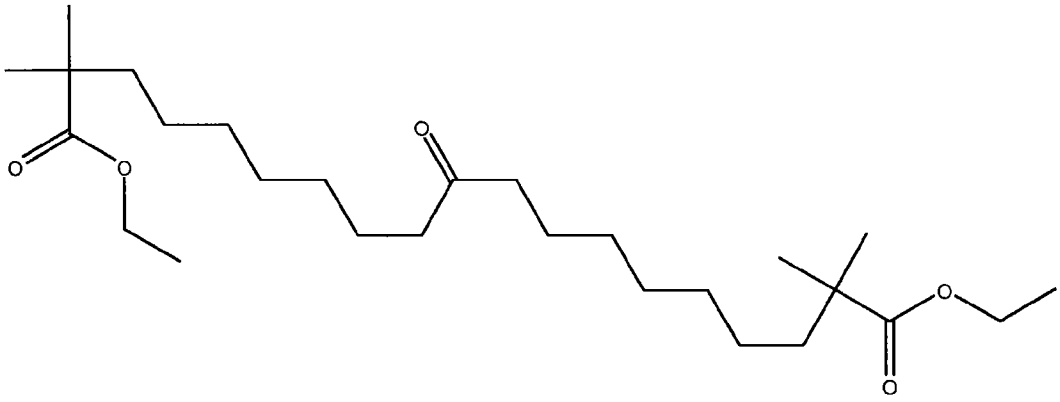
Applicants point out that in the Restriction Requirement dated December 31, 2007, the Examiner did not appear to take into account the Preliminary Amendment dated May 25, 2006 and included in the file on PAIR. The Preliminary Amendment canceled claims 1-8, 10-12, 17-19, 30-33, and 35; amended claims 9, 15, 20, 21, 26, 34, and 36-57; and presented new claims 58-69. There was also an amendment to the specification referencing the prior-filed application. Since the Preliminary Amendment was filed within the later of 4 months from the date the National Stage commenced under 35 U.S.C. 371 or 16 months from the filing of the prior-filed application, Applicants were not required to provide a petition and surcharge to complete the priority claim.

Therefore, Applicants respectfully request the Examiner acknowledge that the Preliminary Amendment dated May 25, 2006 is formerly on the record and that the Restriction Requirement be reconsidered and recast in light thereof and of the amendments made in this Reply.

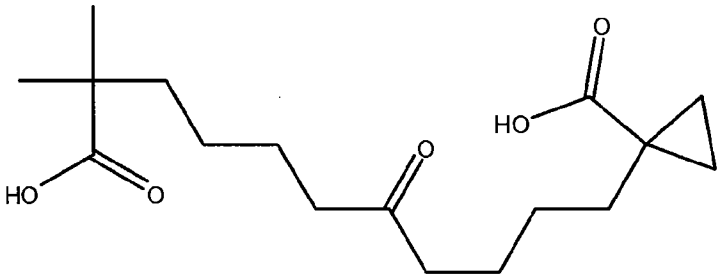
As pointed out previously, the compounds claimed in claims 58 – 69 correspond to compounds 106d, 106n, 107c, 107d, 107e, 107f, 107g, 107k, 107l, 107m, and 107n disclosed in the specification on pages 232, 236- 240, 292, and 293. Therefore, no new matter is presented. The structures of said compounds are as follows:



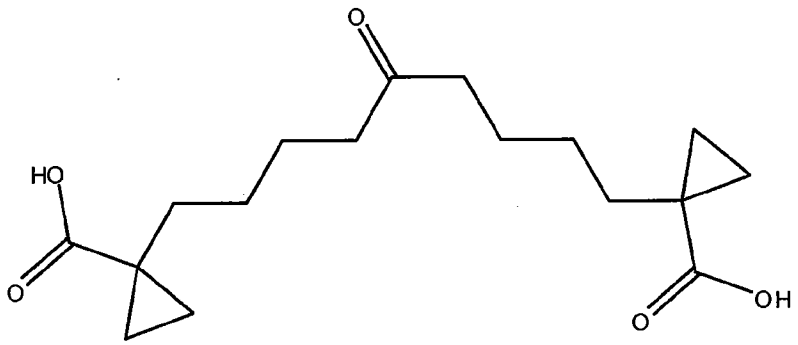
t-butyl-1-[9-[1-(tert-butyloxycarbonyl)cyclopropyl]-5-oxononyl]-1-cyclopropanecarboxylate



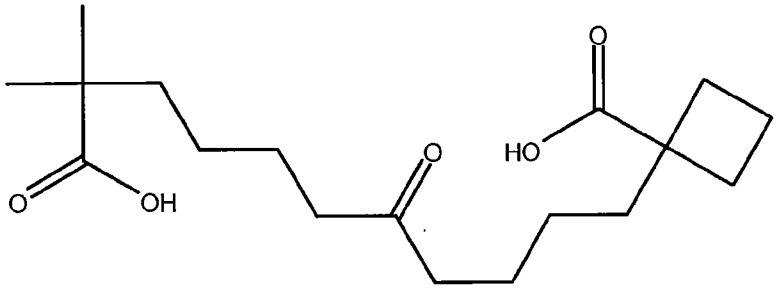
Diethyl 10-oxo-2,2,18,18-tetramethyl-nonadecanedioate



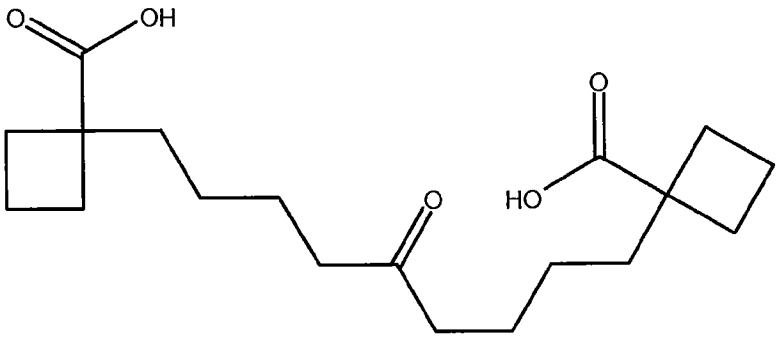
11-(1-Carboxycyclopropyl)-2,2-dimethyl-7-oxoundecanoic acid



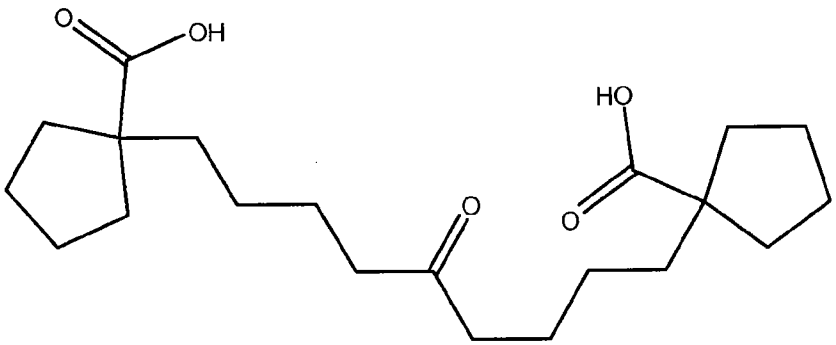
1-[9-(1-Carboxycyclopropyl)-5-oxononyl]-1-cyclopropanecarboxylic acid



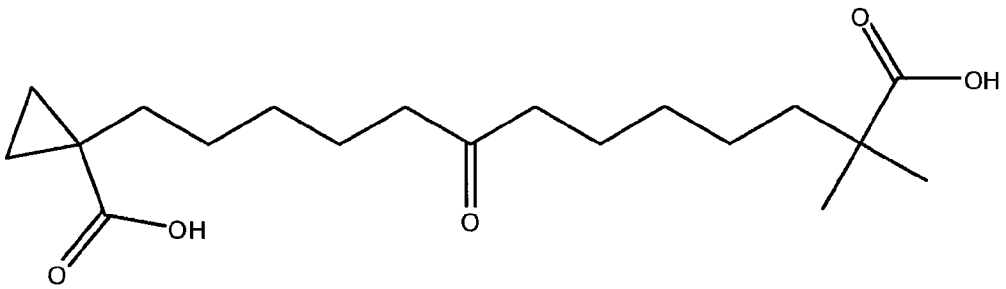
11-(1-Carboxycyclobutyl)-2,2-dimethyl-7-oxoundecanoic acid



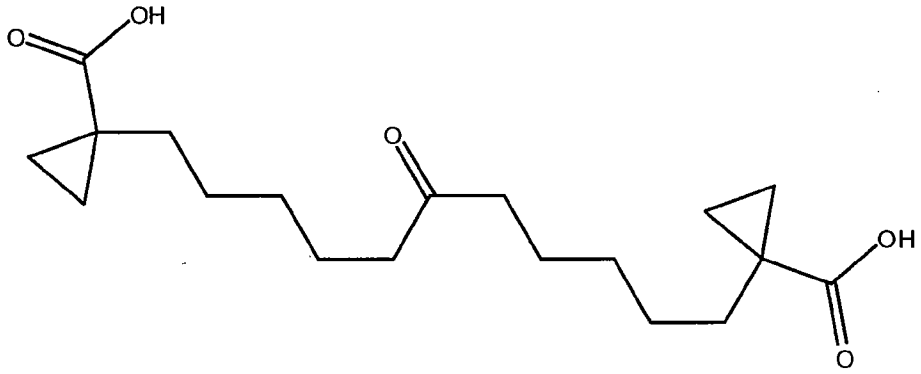
1-[9-(1-Carboxycyclobutyl)-5-oxononyl]-1-cyclobutanecarboxylic acid



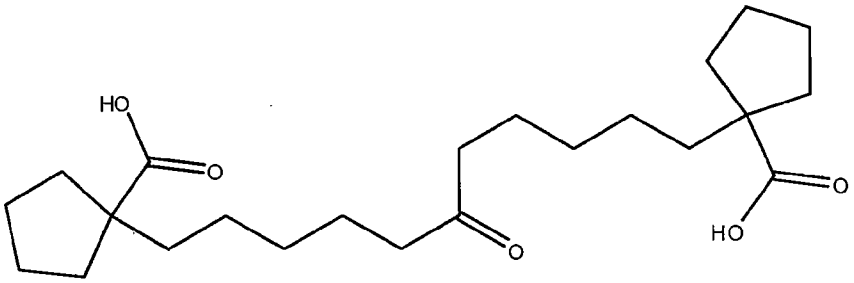
1-[9-(1-Carboxycyclopentyl)-5-oxononyl]-1-cyclopentylcarboxylic acid



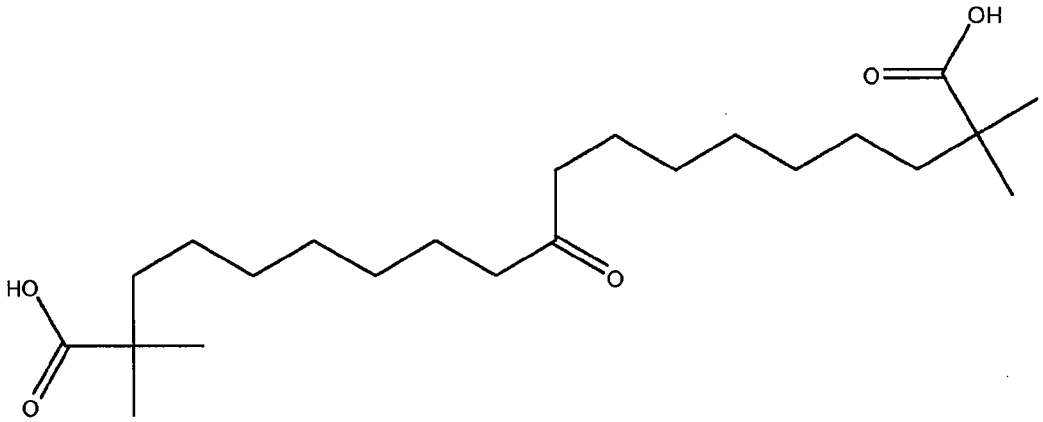
13-(1-Carboxycyclopropyl)-2,2-dimethyl-8-oxotridecanoic acid



1-[11-(1-Carboxycyclopropyl)-6-oxoundecyl]-1-cyclopropane carboxylic acid



1-[11-(1-Carboxycyclopentyl)-6-oxoundecyl]-1-cyclopentane carboxylic acid



10-Oxo-2,2,18,18-tetramethyl-nonadecanedioic acid

In the alternative and to leave no doubt that this Reply is responsive to the pending restriction requirement, Applicants hereby elect Group L, original claims 20, 34, and 35. Group L is defined on page 6 of the Restriction Requirement as:

> L. Claims 20, 34-35, drawn to none of the examples above but other compounds within the scope of the claims. The compounds must be disclosed in the specification. Structures of the compounds must be submitted and if more than one species a generic formula embracing all the species must also be submitted. This group may be subject to further restriction.

The compounds that are elected and covered by the pending claims are drawn to none of the examples above, they are specifically disclosed in the specification, and structures of the compounds are provided above. While a generic formula embracing all of the compounds has not been provided a generic claim listing all of the species has been.

The current pending claims as amended are sufficiently narrow that no restriction is deemed necessary and the method of treatment claims may be considered along with the compound and composition claims without presenting an undue burden on the Examiner.

Pending claims 34, 36, and 56-69, as amended, are patentable. Applicants respectfully request the Examiner grant early allowance of this application. The Examiner is invited to contact the undersigned attorneys for the Applicant via telephone if such communication would expedite this application.

Respectfully submitted,

Dated: June 27, 2008

/WRB/
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EXHIBIT G

Case No. 13657-30
Client Ref. No. PC20667US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Jean-Louis Dasseux et al.	Examiner: Taofiq A. Solola
Serial No: 10/596,047	Group Art Unit: 1625
Filed: June 21, 2006	Conf. No.: 1170
For: Ketone Compounds and Compositions for Cholesterol Management and Related Uses	

AMENDMENT AND REPLY UNDER 37 C.F.R. § 1.111

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed September 30, 2008, Applicants provide the following amendments and comments. An Information Disclosure Statement and a Request for a One-Month Extension of Time is also submitted herewith.

Amendments to the Claims are reflected in the listing of the claims which begin on page 2 of this paper.

Remarks begin on page 8 of this paper.

Applicants note that the Transmittal to which this paper is attached includes a Certificate of Electronic Transmittal under 37 C.F.R § 1.8; and a fee statement calculating any fee(s) presently due in connection with the filing of this paper, along with an authorization to charge any fee deficiency to Deposit Account No. 23-1925.

In the Claims:

Please amend the Claims as follows (the changes in these Claims are shown with ~~strikethrough~~ for deleted matter and underlines for added matter). A complete listing of the claims with proper claim identifiers is set forth below.

Claims 1 – 57 (cancelled).

Claim 58 (currently amended). A compound or pharmaceutically acceptable salt, hydrate, or solvate thereof selected from:

t-Butyl 1-[9-[1-(tert-butoxycarbonyl)cyclopropyl]-5-oxononyl]-1-cyclopropanecarboxylate,

Diethyl 10-oxo-2,2,18,18-tetramethyl-nonadecanedioate,

11-(1-carboxycyclopropyl)-2,2-dimethyl-7-oxoundecanoic acid ;

1-[9-(1-carboxycyclopropyl)-5-oxononyl]-1-cyclopropanecarboxylic acid;

~~11-(1-carboxycyclopropyl)-2,2-diemethyl-7-oxoundecanoic acid ;~~

~~1-[9-(1-carboxycyclopropyl)-5-oxononyl]-1-cyclopropanecarboxylic;~~

11-(1-Carboxycyclobutyl)-2,2-dimethyl-7-oxoundecanoic acid,

1-[9-(1-Carboxycyclobutyl)-5-oxononyl]-1-cyclobutanecarboxylic acid,

1-[9-(1-Carboxycyclopentyl)-5-oxononyl]-1-cyclopentylcarboxylic acid,

13-(1-Carboxycyclopropyl)-2,2-dimethyl-8-oxotridecanoic acid,

1-[11-(1-Carboxycyclopropyl)-6-oxoundecyl]-1-cyclopropane carboxylic acid,

1-[11-(1-Carboxycyclopentyl)-6-oxoundecyl]-1-cyclopentane carboxylic acid,

10-Oxo-2,2,18,18-tetramethyl-nonadecanedioic acid.

Claim 59 (previously presented). A compound of claim 58 wherein said compound is *t*-Butyl 1-[9-

[1-(tert-butoxycarbonyl)cyclopropyl]-5-oxononyl]-1-cyclopropanecarboxylate, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 60 (previously presented). A compound of claim 58 wherein said compound is Diethyl 10-oxo-2,2,18,18-tetramethyl-nonadecanedioate, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 61 (currently amended). A compound of claim 58 wherein said compound is ~~11-(1-Carboxycyclopropyl)-2,2-diemethyl-7-oxoundecanoic acid,~~ 11-(1-carboxycyclopropyl)-2,2-dimethyl-7-oxoundecanoic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 62 (previously presented). A compound of claim 58 wherein said compound is 1-[9-(1-Carboxycyclopropyl)-5-oxononyl]-1-cyclopropanecarboxylic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 63 (previously presented). A compound of claim 58 wherein said compound is 11-(1-Carboxycyclobutyl)-2,2-dimethyl-7-oxoundecanoic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 64 (previously presented). A compound of claim 58 wherein said compound is 1-[9-(1-Carboxycyclobutyl)-5-oxononyl]-1-cyclobutanecarboxylic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 65 (previously presented). A compound of claim 58 wherein said compound is 1-(9-(1-

Carboxycyclopentyl)-5-oxononyl]-1-cyclopentylcarboxylic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 66 (previously presented). A compound of claim 58 wherein said compound is 13-(1-

Carboxycyclopropyl)-2,2-dimethyl-8-oxotridecanoic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 67 (previously presented). A compound of claim 58 wherein said compound is 1-[11-(1-

Carboxycyclopropyl)-6-oxoundecyl]-1-cyclopropane carboxylic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 68 (previously presented). A compound of claim 58 wherein said compound is 1-[11-(1-

Carboxycyclopentyl)-6-oxoundecyl]-1-cyclopentane carboxylic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 69 (previously presented). A compound of claim 58 wherein said compound is 10-Oxo-

2,2,18,18-tetramethyl-nonadecanedioic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 70 (new). A pharmaceutical composition comprising a compound of claim 58 or a pharmaceutically acceptable salt, hydrate, or solvate thereof and a pharmaceutically acceptable carrier.

Claim 71 (new). A method of increasing HDL levels, which comprises administering to a patient in need of such treatment a therapeutically effective amount of a compound pharmaceutically acceptable salt, hydrate, or solvate thereof selected from:

t-Butyl 1-[9-[1-(tert-butoxycarbonyl)cyclopropyl]-5-oxononyl]-1-cyclopropanecarboxylate,

Diethyl 10-oxo-2,2,18,18-tetramethyl-nonadecanedioate,

11-(1-carboxycyclopropyl)-2,2-dimethyl-7-oxoundecanoic acid ;

1-[9-(1-carboxycyclopropyl)-5-oxononyl]-1-cyclopropanecarboxylic acid;

11-(1-Carboxycyclobutyl)-2,2-dimethyl-7-oxoundecanoic acid,

1-[9-(1-Carboxycyclobutyl)-5-oxononyl]-1-cyclobutanecarboxylic acid,

1-[9-(1-Carboxycyclopentyl)-5-oxononyl]-1-cyclopentylcarboxylic acid,

13-(1-Carboxycyclopropyl)-2,2-dimethyl-8-oxotridecanoic acid,

1-[11-(1-Carboxycyclopropyl)-6-oxoundecyl]-1-cyclopropane carboxylic acid,

1-[11-(1-Carboxycyclopentyl)-6-oxoundecyl]-1-cyclopentane carboxylic acid,

10-Oxo-2,2,18,18-tetramethyl-nonadecanedioic acid.

Claim 72 (new). A method according to claim 71 wherein the compound is 11-(1-carboxycyclopropyl)-2,2-dimethyl-7-oxoundecanoic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 73 (new). A method according to claim 71 wherein the compound is 1-[9-(1-carboxycyclopropyl)-5-oxononyl]-1-cyclopropanecarboxylic acid or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 74 (new). A method according to claim 71 wherein the compound is 11-(1-carboxycyclobutyl)-2,2-dimethyl-7-oxoundecanoic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 75 (new). A method according to claim 71 wherein the compound is 1-[9-(1-carboxycyclobutyl)-5-oxononyl]-1-cyclobutanecarboxylic acid or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 76 (new). A method of decreasing LDL levels, which comprises administering to a patient in need of such treatment a therapeutically effective amount of a compound pharmaceutically acceptable salt, hydrate, or solvate thereof selected from:

t-Butyl 1-[9-[1-(tert-butoxycarbonyl)cyclopropyl]-5-oxononyl]-1-cyclopropanecarboxylate,

Diethyl 10-oxo-2,2,18,18-tetramethyl-nonadecanedioate,

11-(1-carboxycyclopropyl)-2,2-dimethyl-7-oxoundecanoic acid ;

1-[9-(1-carboxycyclopropyl)-5-oxononyl]-1-cyclopropanecarboxylic acid;

11-(1-Carboxycyclobutyl)-2,2-dimethyl-7-oxoundecanoic acid,

1-[9-(1-Carboxycyclobutyl)-5-oxononyl]-1-cyclobutanecarboxylic acid,

1-[9-(1-Carboxycyclopentyl)-5-oxononyl]-1-cyclopentylcarboxylic acid,

13-(1-Carboxycyclopropyl)-2,2-dimethyl-8-oxotridecanoic acid,

1-[11-(1-Carboxycyclopropyl)-6-oxoundecyl]-1-cyclopropane carboxylic acid,

1-[11-(1-Carboxycyclopentyl)-6-oxoundecyl]-1-cyclopentane carboxylic acid,

10-Oxo-2,2,18,18-tetramethyl-nonadecanedioic acid.

Claim 77 (new). A method according to claim 76 wherein the compound is 11-(1-carboxycyclopropyl)-2,2-dimethyl-7-oxoundecanoic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 78 (new). A method according to claim 76 wherein the compound is 1-[9-(1-carboxycyclopropyl)-5-oxononyl]-1-cyclopropanecarboxylic acid or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 79 (new). A method according to claim 76 wherein the compound is 11-(1-carboxycyclobutyl)-2,2-dimethyl-7-oxoundecanoic acid, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

Claim 80 (new). A method according to claim 76 wherein the compound is 1-[9-(1-carboxycyclobutyl)-5-oxononyl]-1-cyclobutanecarboxylic acid or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

REMARKS

Claims 58–69, as amended, and new claims 70–80 are pending in the application. Claims 36, 56, and 57 are canceled without prejudice. The amendment to claim 58 was made to correct typographical errors. Support for the chemical names is found in the specification on pages 232, 236–240, 292, and 293. New claim 70 is of the exact same scope as previous claim 34. New method claims 71 and 76 find support in the specification on pages 196–197. Dependent claims 72–75 and 77–80 limit claims 71 and 76, respectively, by naming a single compound which is claimed per se in earlier claims and supported in the specification. Therefore, no new matter is added with the amendments or the new claims.

Claims 36, 56, and 57 stand rejected under 35 U.S.C. 112, first paragraph as allegedly failing to comply with the written description requirement. The Examiner alleges that methods describing "disorders capable of being treated or prevented by increasing HDL or decreasing LDL levels" or "cardiovascular disease" are "reach-through claims", do not represent practical utilities and are not patentable under current practice. Applicants respectfully disagree.

Without acquiescing to the rejection, but in order to facilitate prosecution, applicants have canceled claims 36, 56, and 57 and replaced them with new claims 71–80. New claims 71–80 relate to methods of increasing HDL or decreasing LDL in a patient in need thereof comprising the administration of the compounds listed herein. Increasing HDL and decreasing LDL are therapeutically beneficial and are recognized, practical utilities. These utilities are demonstrated, for example, in Tables 6 and 8 of the specification. Applicants point out that each compound listed in claims 71–80 are named in the specification on pages 232, 236–240, 292, and 293. The specification also teaches on pages 196–197 that the compounds of the invention raise HDL and lower LDL. Since the specification clearly teaches the specific compounds and the specific utilities of raising HDL and lowering LDL, applicants clearly had possession of the claimed invention at the filing date.

Therefore, claims 71–80 satisfy the written description requirement under 35 USC 112, first paragraph. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claims 36, 56, and 57 stand rejected under 35 U.S.C. 112, first paragraph as allegedly lacking enablement. In applying the Wands factors, the Examiner alleges that the breadth of the claims includes many compounds broadly taught to treat or prevent all cardiovascular diseases or disorders capable of being treated or prevented by increasing HDL or decreasing LDL levels. The Examiner acknowledges that the compounds are useful for treating dyslipidemia but argues that not every instance of lipidemia leads to all known cardiovascular diseases. The Examiner also argues that the specification fails to disclose how normal patients "who are predisposed to these unnamed diseases would be identified and treated before developing the unnamed diseases." Applicants respectfully traverse the rejection.

Without acquiescing to the rejection, applicants cancel claims 36, 56, and 57 and replace them with new claims 71–80. As related above, claims 71–80 relate to methods of increasing HDL or decreasing LDL in a patient in need thereof comprising administering a small group of compounds set forth in claims 71 and 76. The specification clearly sets forth how to make the compounds as set forth in the synthetic examples, for example, on pages 232–240 and in the generic synthetic schemes provided on pages 141–193 of the specification. Further, the specification sets forth how to formulate and administer the compounds on pages 216–222.

Table 8 on page 296 of the specification sets forth the effects of nine of the compounds on nonHDL cholesterol, HDL cholesterol, triglyceride levels, glycemic control indicators and body weight control in Obese Female Zucker Rats. Table 6 on pages 292 and 293 further sets forth the effects of the same nine compounds on lipid synthesis in primary rat hepatocytes. The compounds clearly demonstrate pharmacological effects that represent patentable utility.

Regarding the Examiner's questioning how one would identify appropriate patients, applicants submit that such an action is well within the skill of the ordinary clinician. There are numerous LDL-lowering drugs on the market including several in the statin class such as lovastatin, simvastatin, atorvastatin, rosuvastatin, and the like. Some of these drugs, e.g. rosuvastatin also possess HDL-raising properties. Clinicians are well aware of how to identify appropriate patients for the claimed compounds.

Applicants submit that the specification clearly sets forth how to make and use the claimed invention without undue experimentation. Therefore, the pending claims satisfy the enablement requirement. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claims 36, 56, and 57 stand rejected under 35 U.S.C. 112, second paragraph as allegedly being indefinite. The Examiner does not provide any reasons why the claims are allegedly indefinite, but merely states that the same reasons used for arguing that the claims lack written description support and enablement under 35 U.S.C. 112, first paragraph render the claims indefinite. Applicants respectfully disagree. The standard for indefiniteness is that the claims must be insolubly ambiguous. Claims can lack enablement and perhaps lack written description but still be definite.

Without acquiescing to the rejection, applicants submit that new claims 71–80 are definite. The claims relate to a method of either increasing HDL or reducing LDL (established beneficial pharmacological effects) in a patient in need thereof using a small and discreet group of compounds. Applicants respectfully request that the indefiniteness rejection under 35 U.S.C. 112, second paragraph be reconsidered and withdrawn.

The Examiner has determined that claims 58–69 are allowable over the prior art of record but indicates that applicants must delete any overlap with related U.S. Patents 6,699,910; 7,304,092; 7,119,221; 7,335,689; and 7,335,799. Applicants

confirm that there is no overlap between the pending claims and the claims of any of said patents.

The Examiner also requests that a brief description of the drawings be provided in the specification. Applicants direct the Examiner's attention to page 132, section 3.1 of the specification entitled "Brief Description of the Drawings." Applicants do not believe additional description is necessary.

Claims 58–69, as amended, and new claims 71–80 are patentable. Applicants respectfully request the Examiner grant early allowance of this application. The Examiner is invited to contact the undersigned attorneys for the Applicant via telephone if such communication would expedite this application.

Respectfully submitted,

Dated: January 29, 2009

/William R. Boudreaux/
William R. Boudreaux, Reg. No. 35,796
Attorney for Applicants

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